The Negotiated Rulemaking Committee on Special Payment Provisions for Prosthetics and Certain Custom-Fabricated Orthotics Meeting

June 2-3, 2003 – Meeting #8

Day 1 – June 2, 2003

The Negotiated Rulemaking Committee on Special Payment Provisions for Prosthetics and Certain Custom-Fabricated Orthotics convened on June 2, 2003, at the Pikesville Hilton in Pikesville, Maryland for its eighth meeting. Shortly after 9:15 a.m., Commissioners Lynn Sylvester and Ira Lobel with the Federal Mediation and Conciliation Services (FMCS) called the meeting to order and distributed the sign-in sheet (Attachment 8.1) and agenda (Attachment 8.2). Ms. Sylvester reviewed the minutes from the last meeting with the committee. The minutes were approved as noted (Attachment 8.3). After taking a brief caucus to discuss a consolidated report generated by various committee members proposing a tentative committee agreement (Attachment 8.4), the committee reconvened to discuss the document in open forum. It was noted that CMS had reviewed the document and provided edits (primarily technical edits) to the facilitators. The significant changes to the tentative agreement were as follows:

- Specific references to hospitals and SNFs were deleted.
- Various L-codes were deleted.
- Issues of qualified suppliers were clarified.
- Scenarios describing central fabrication and manufacturing facilities were combined.

In addition, the committee agreed that CMS would address the issue of "artificial eyes" as a prosthetic under the new regulation. CMS also informed the committee that it could split the list of L-codes into an "A" and "B" list depending on how an item is fabricated. In response to this suggestion, Stuart Kurlander, National Orthotic Manufacturers Association (NOMA), offered that NOMA's methodology for addressing the issue of L-codes may negate the need to have multiple lists. Julie Kass, American Occupational Therapy Association (AOTA), added that she would object to several codes if the committee did not reach consensus on physical therapists and occupational therapists being considered qualified practitioners according to the statute. It was also suggested that a number of codes be removed from the list (because the fabrication of such items was not highly complex).

The facilitators worked to address/incorporate these and other suggestions into a revised version of the draft agreement during lunch. An updated version of the agreement is provided as Attachment 8.5. Following lunch, the committee was also asked to caucus to review a modified agreement proposed by several of the O&P organizations on the committee (Attachment 8.6). Shortly before 5:00 p.m., the committee reconvened to discuss and compare the updated draft agreement and the agreement proposed by the

O&P committee members. The committee generated various scenarios to fully explore issues and arrive at a common understanding regarding patient responsibility, supplier standards, billing parties, and other items. It was noted that CMS informed the committee that its existing billing forms may not accommodate a scenario in which a qualified practitioner (QP) uses a central fabrication facility that meets all supplier, DEMPOS, and ABC/BOC requirements to fabricate an item and the QP bills Medicare. The working agreement, as updated by the facilitators, is provided as Attachment 8.7.

Mr. Ted Colaizzi, C.Ped representative, also made a brief presentation to the committee on the first day (See Item Nine of Attachment 8.6).

Day 2 – June 3, 2003

The second day of the Negotiated Rulemaking Committee on Special Payment Provisions for Prosthetics and Certain Custom-Fabricated Orthotics opened with Mr. Lobel leading the committee through a review of the updated tentative agreement. Item numbers 3, 4, 6, 10, and 11 were preliminarily approved without further modification. Item 7 was approved as noted and items 8 and 9 required further modifications. The remainder of the items was not addressed on the second day. (Please refer to Attachment 8.7 for updates to the draft agreement.)

The committee took a short caucus to review the latest version of the agreement. When they reconvened, they revisited the issue of conditions of being a qualified supplier. Terry Supan, State Boards, inquired about facility requirements for OT/PTs in private practice. In response to his question, Ms. Kass directed the group to the following regulations: 42 CFR 486 subpart D; and 42 CFR 410.59, 410.60, and 410.61. Other questions posed by the committee were as follows:

Q: Does ABC and/or BOC specify the particular types of equipment a facility needs to have to meet accreditation requirements?
A: Both ABC and BOC state that the facility must have equipment that is appropriate for the services to be rendered and a capacity to make adjustments as needed.

Q: Do PT/OT practices have rules for repair and replacement of devices?
A: Yes. We are compelled to have facilities adequately prepared for services we provide. Specifics can be found in the statutory references previously provided.

Q: Does Section 427 of BIPA apply to payment rules for participation only via the DMERC pathway?
A: It applies to when reimbursement is sought under Medicare Part B. Section 427 is an amendment to Section 1834 of the Social Security Act. It is strictly a Part B provision. There are payment exclusionary rules that are listed.

Q: Kim Doolan of the Barr Foundation asked, “Can we expand the text in item 8c (See Attachment 8.7) because one entity could have a single qualified practitioner and provide 400,000 devices?”

A: Stuart Kurlander, NOMA, responded, "I don't see a need to expand the definition. It should not make a difference if the entity makes 1, 100, or 100,000 devices."

Although some members of the committee remained concerned about facility standards, CMS reminded the committee that, per the statute, the third pathway is one the Secretary determines appropriate (not necessarily the committee). This statement prompted the question of whether or not a new entity looking for acceptance as the third pathway would be compared to or held to similar standards required by ABC and BOC. To this, CMS responded yes, it would make sure the standards were equivalent. A member of the committee asked that the committee undertake the exercise of comparing FDA requirements (potentially a third pathway for manufacturers) and the third pathway proposed by OT/PTs against ABC and BOC facility requirements/standards. It was stated that CMS would conduct a valid assessment comparison for all entities wishing to become a third pathway.

Following a break for lunch, Ms. Sylvester stated that the last couple of committee meetings had been particularly productive. She felt, however, that the committee would need one additional meeting to complete its work. She asked the committee members to check their calendars for a meeting on July 14, 2003. The alternative date was set for September 8, 2003.

Next, Joel Kaiser, CMS Health Insurance Specialist discussed the issue of L-codes with the committee (See Attachment 8.8). The L-code document was updated to reflect edits suggested by various committee members, including a change in the language to read, "any custom fabricated orthoses that involves multiple joints (not multiple articular surfaces) can be considered for inclusion on the list. However, for the purposes of BIPA 427 (and only for this purpose) the hand and wrist together (excluding fingers and thumb) shall be considered one joint." This text was preliminarily approved after committee members assured CMS that the NPRM text would not leave off items that are molded over the patient model for possible inclusion on the list. Mr. Kaiser stated that the guiding principles developed by the committee would be used by CMS to update the list of L-codes in the future. CMS noted that it does not intend to go through the notice and comment rulemaking process again to add L-codes to the list. In response to this statement, Ms. Kass reiterated that she could only agree with the second item if PT/OTs were considered qualified practitioners. The second item reads:

> *Any custom fabricated orthosis that is fabricated directly on the patient requires that specialized skills of a qualified practitioner and therefore HCPCS codes describing such orthosis should be included on the list. (Fabrication directly on the patient means actual construction of the item and not simply minor modifications.)*

Mr. Kaiser went on to clarify that an item cannot be on the list if it is not individually fabricated over a positive model of the patient. He asked the committee to confirm that all the items on the list are molded over a positive model of the patient. He was told that

every code (item) on the list could be molded over a positive model of the patient. Some can be done this way but are not always done this way. Other items that can be done this way but are not always done this way are not on the list. To bring this issue to closure, CMS agreed to finalize the list of L-codes for the committee to review. Before moving on, NOMA representatives stated they could not agree to moving any code (item) to a miscellaneous code or altering the codes in any way unless there was overall agreement on the negotiated rulemaking. Cathy Ellis, American Physical Therapy Association (APTA) added, her group could not make a final decision on the issue of L-codes until the committee finalized the issue of qualified provider. Finally, there was a request that Mr. Kaiser document any issues/concerns he had regarding the L-codes well in advance of the next meeting.

After a short break, there was a request that the committee provide a definition for the term "template" referenced in the fourth item: Orthoses that are fabricated over templates are not included on the Secretary's list because they are not fabricated over a positive model of the patient.

Before ending the meeting, the facilitators recapped the outstanding issues that remained for the next meeting. These items were as follows:

- Items 1, 2, and 5 on the tentative agreement.
- A definition of template.
- CMS will look at Item 8 on the tentative agreement (and compare ABC/BOC standards with third pathway possibilities).

In addition to these items, Mr. Kurlander agreed to send a memorandum to the committee on FDA regulations and APTA agreed to email conditions of participation for PT/OTs in all settings to Ms. Sylvester, who will forward the information to the committee members. Ms Sylvester also indicated she would mail committee members copies of the public comment letters she has received.

Finally, Ms. Sylvester asked that for the sake of the negotiation process, the committee members refrain from posting comments to websites or writing articles that may derail the progress the group has made. She encouraged the committee members to direct their constituents to CMS' website for a copy of the meeting minutes for an update on the committee's progress.

The meeting was adjourned at 3:35 p.m.

List of Attachments

Attachment 8.1	Sign-In Sheet
Attachment 8.2	Agenda
Attachment 8.3	Final Minutes Meeting #7
Attachment 8.4	Draft Agreement
Attachment 8.5	Draft Agreement Update #2
Attachment 8.6	O&P Proposed Agreement
Attachment 8.7	Draft Agreement Update #3
Attachment 8.8	L-code Document
Attachment 8.9	Letter from National Commission on Orthotic and Prosthetic Education (NCOPE)

CMS Special Payment Provisions for Prosthetics

And

Certain Custom-Fabricated Orthotics Negotiated Rulemaking

Proposed by the O&P Negotiated Rulemaking Committee Organizations

1. CMS will include the following in the regulations text of the Notice of Proposed Rulemaking (NPRM):

   Every "Qualified Practitioner," as defined in section 427 of BIPA and in these regulations, must personally ensure that he/she is competent to design, fit, fabricate and furnish prostheses and certain orthoses that are identified on the list of items that will be included as an attachment to the NPRM prior to providing it to a specific patient.

   "Qualified Physical Therapists" and "Qualified Occupational Therapists" who design, fit, and fabricate prostheses and certain orthoses that are identified on the list of items that will be included as an attachment to the NPRM, will have education and training directly related to the provision of these services for which Medicare reimbursement is sought.

2. In the text of the NPRM, CMS will define the terms "Qualified Physical Therapist" and "Qualified Occupational Therapist" to be the same as the definitions for physical therapist and occupational therapist found in 42 CFR § 484.4 (Personnel Qualifications).

3. In the text of the NPRM, CMS will define the term "certified by ABC or BOC" to be the same as the definitions for Prosthetist and Orthotist found in 42 CFR § 485.70 (Personnel Qualifications).

4. The parties agree that the term "prosthetics" within BIPA Section 427 means "prostheses" and which are identified as artificial arms, legs, and eyes, including replacements because of a change in the patient's physical condition.

5. The parties agree that the term "orthotics" within BIPA Section 427 means "orthoses" and which are identified as leg, arm, back, and neck braces, including replacements because of a change in the patient's physical condition.

6. The parties agree to the following with respect to the intent of BIPA Section 427 regarding “Payment Provisions and Requirements for Prosthetics and Certain Custom-Fabricated Orthotics.”

   The Payment Rules for the provision of prosthetic and certain custom fabricated orthotic devices require that they be furnished by a “Qualified Practitioner.”

   The Payment Rules for the provision of prosthetic and certain custom fabricated orthotic devices require that they be fabricated by a “Qualified Practitioner” or a “Qualified Suppler” (i.e., ABC or BOC Accredited Facility).

   The description of a custom fabricated orthotic device is molded to a patient model item that requires education, training, and experience to fabricate.

   The established list of certain custom fabricated orthotic items shall not include shoes or shoe inserts.

7. The parties agree to the following with respect to the intent of “Qualified Practitioners” and “Qualified Suppliers” under Payment Rules of BIPA Section 427 who custom fabricate prostheses and certain custom fabricated model orthoses:

   Custom fabricated prosthetic devices and certain custom fabricated orthotic devices must be provided by a “Qualified Practitioner.”

   A “Qualified Practitioner” or “Qualified Supplier,” whether they are a Licensed or Certified, Orthotist, Prosthetist, Physical Therapist, Occupational Therapist or Physician, must meet the applicable regulations for providing orthotics and prosthetics care under 42 CFR 424.57: “Special payment rules for items furnished by DMEPOS suppliers and issuance of DMEPOS supplier billing privileges”

   A “Qualified Practitioner” or “Qualified Supplier” must have a DMEPOS Supplier Number in accordance with existing Federal statutes and CMS regulations to receive payment for the provision of orthotic and prosthetic services.

   A “Qualified Practitioner” or “Qualified Supplier” must meet such criteria as the Secretary determines appropriate to provide custom fabricated prostheses or certain orthoses included in a list established by the Secretary, which does not include shoes and shoe inserts.

   A “Qualified Practitioner” may be credentialed by and approved by a Program that the Secretary determines, in consultation with appropriate experts in orthotics and prosthetics, has training and education standards that are necessary to provide such prostheses and orthoses.

   An orthotic and/or prosthetic “Qualified Practitioner” must be licensed as a Prosthetist and/or Orthotist in states where individuals cannot provide prostheses and/or orthoses unless they are licensed under state law.

   A “Qualified Supplier” may be accredited and approved by a Program that the Secretary determines has met accreditation and approval standards that are essentially equivalent to those of ABC or BOC.

A Central Fabrication Facility or Manufacturer of custom fabricated orthotic and prosthetic devices cannot be recognized as a “Qualified Supplier” without meeting the Payment Rules of BIPA Section 427.

8. The parties agree that all of the Prosthetic HCPCS L-Codes, as well as following Orthotic HCPCS Base L-Codes will be covered by the statute:

HCPCS Code	PROCEDURE DESCRIPTOR
L0100	Cranial orthosis (helmet), with or without soft interface, molded to patient model
L0130	Cervical, flexible, thermoplastic collar, molded to patient
L0170	Cervical, collar, molded to patient model

HCPCS Code	PROCEDURE DESCRIPTOR
L0480	TLSO, triplanar control, one piece rigid plastic shell without interface liner, with multiple straps and closures, posterior extends from sacrococcygeal junction and terminates just inferior to scapular spine, anterior extends from symphysis pubis to sternal notch, anterior or posterior opening, restricts gross trunk motion in sagittal, coronal, and transverse planes, includes a carved plaster or CAD-CAM model, custom fabricated
L0482	TLSO, triplanar control, one piece rigid plastic shell with interface liner, multiple straps and closures, posterior extends from sacrococcygeal junction and terminates just inferior to scapular spine, anterior extends from symphysis pubis to sternal notch, anterior or posterior opening, restricts gross trunk motion in sagittal, coronal, and transverse planes, includes a carved plaster or CAD-CAM model, custom fabricated
L0484	TLSO, triplanar control, two piece rigid plastic shell without interface liner, with multiple straps and closures, posterior extends from sacrococcygeal junction and terminates just inferior to scapular spine, anterior extends from symphysis pubis to sternal notch, lateral strength is enhanced by overlapping plastic, restricts gross trunk motion in the sagittal, coronal, and transverse planes, includes a carved plaster or CAD-CAM model, custom fabricated
L0486	TLSO, triplanar control, two piece rigid plastic shell with interface liner, multiple straps and closures, posterior extends from sacrococcygeal junction and terminates just inferior to scapular spine, anterior extends from symphysis pubis to sternal notch, lateral strength is enhanced by overlapping plastic, restricts gross trunk motion in the sagittal, coronal, and transverse planes, includes a carved plaster or CAD-CAM model, custom fabricated
L0550	LSO, anterior-posterior-lateral control, molded to patient model
L0560	LSO, anterior-posterior-lateral control, molded to patient model, with interface material
L0700	CTLSO, anterior-posterior-lateral control, molded to patient model (Minerva type)
L0710	CTLSO, anterior-posterior-lateral control, molded to patient model, with interface material (Minerva type)
L0810	Halo procedure, cervical halo incorporated into jacket vest
L0820	Halo procedure, cervical halo incorporated into plaster body jacket
L0830	Halo procedure, cervical halo incorporated into Milwaukee type orthosis
L1000	CTLSO (Milwaukee), inclusive of furnishing initial orthosis, including model
L1200	TLSO, inclusive of furnishing initial orthosis only
L1300	Other scoliosos procedure, body jacket, molded to patient model
L1310	Other scoliosos procedure, post-operative body jacket
L1630	HO, abduction control of hip joints, semi-flexible (Von Rosen type), custom fabricated
L1640	HO, abduction control of hip joints, static, pelvic band or spreader bar, thigh cuffs, custom fabricated
L1680	HO, abduction control of hip joints, dynamic, pelvic control, adjustable hip motion control, thigh cuffs (Rancho hip action type), custom fabricated
L1685	HO, abduction control of hip joint, postoperative hip abduction type, custom fabricated
L1700	Legg Perthes orthosis, (Toronto type), custom fabricated
L1710	Legg Perthes orthosis, (Newington type), custom fabricated
L1720	Legg Perthes orthosis, trilateral, (Tachdijan type), custom fabricated
L1730	Legg Perthes orthosis, (Scottish Rite type), custom fabricated
L1755	Legg Perthes orthosis, (Patten bottom type), custom fabricated
L1904	AFO, molded ankle gauntlet, custom fabricated
L1940	AFO, plastic or other material, custom fabricated
L1945	AFO, plastic, rigid anterior tibial section (floor reaction), custom fabricated

HCPCS Code	PROCEDURE DESCRIPTOR
L1950	AFO, spiral, (IRM type), plastic, custom fabricated
L1960	AFO, posterior solid ankle, plastic, custom fabricated
L1970	AFO, plastic with ankle joint, custom fabricated
L2000	KAFO, single upright, free knee, free ankle, solid stirrup, thigh and calf band/cuffs (single bar "AK" orthosis), custom fabricated
L2010	KAFO, single upright, free ankle, solid stirrup, thigh and calf band/cuffs (single bar "AK" orthosis), without knee joint, custom fabricated
L2020	KAFO, double upright, free ankle, solid stirrup, thigh and calf band/cuffs (double bar "AK" orthosis), custom fabricated
L2030	KAFO, double upright, free ankle, solid stirrup, thigh and calf band/cuffs (double bar "AK" orthosis), without knee joint, custom fabricated
L2036	KAFO, full plastic, double upright, free knee, custom fabricated
L2037	KAFO, full plastic, single upright, free knee, custom fabricated
L2038	KAFO, full plastic, without knee joint, multi-axis ankle, (Lively orthosis or equal), custom fabricated
L2039	KAFO, full plastic, single upright, poly-axial hinge, medial lateral rotation control, custom fabricated
~~L2102~~	~~AFO, fracture orthosis, tibial fracture cast orthosis, plaster type casting material, custom fabricated~~
~~L2104~~	~~AFO, fracture orthosis, tibial fracture cast orthosis, synthetic type casting material, custom fabricated~~
L2108	AFO, fracture orthosis, tibial fracture cast orthosis, custom fabricated
~~L2122~~	~~KAFO, fracture orthosis, femoral fracture cast orthosis, plaster type casting material, custom fabricated~~
~~L2124~~	~~KAFO, fracture orthosis, femoral fracture cast orthosis, synthetic type casting material, custom fabricated~~
L2128	KAFO, fracture orthosis, femoral fracture cast orthosis, custom fabricated
L3800	WHFO, short opponens, no attachment, custom fabricated
L3805	WHFO, long opponens, no attachment, custom fabricated
L3900	WHFO, dynamic flexor hinge, reciprocal wrist extension/flexion, finger flexion/extension, wrist or finger driven, custom fabricated
L3901	WHFO, dynamic flexor hinge, reciprocal wrist extension/flexion, finger flexion/extension, cable driven, custom fabricated
L3902	WHFO, external powered, compressed gas, custom fabricated
L3904	WHFO, external powered, electric, custom fabricated
L3906	WHO, wrist gauntlet, custom fabricated
L3907	WHFO, wrist gauntlet with thumb spica, custom fabricated
L3963	SEWHO, molded shoulder, arm, forearm and wrist, with articulating elbow joint, custom fabricated
L3985	Upper extremity fracture orthosis, forearm, hand with wrist hinge, custom fabricated

9. The parties agree that the following HCPCS Base Codes may also be provided by individuals credentialed as a Certified Pedorthist by the Board for Certification in Pedorthics (BCP) or licensed as a Pedorthist by a State Practice Act.

   HCPCS Code:

   L1904 AFO, molded ankle gauntlet, custom fabricated
   L5000 Partial foot, shoe insert with longitudinal arch, toe filler

10. The parties agree that “addition to” Orthotic HCPCS Codes will be covered by the statute when they are used in combination with a base code covered by the statute.

11. The parties agree that the Secretary may determine alternative or additional criteria for “Qualified Practitioner” and “Qualified Supplier” for ocular prostheses, penile prostheses, and mastectomy prostheses and the prosthetic supplies used with them.

12. The parties agree to the following as it relates to the establishment of future HCPCS Codes and their inclusion in the list of prostheses and certain custom fabricated orthoses which will be covered by the statute:

    All future prosthetic codes will be covered by the statute.

    All future orthotic codes which describe an orthosis which is fabricated over a three-dimensional model of a patient’s body segment, created from a positive impression or a computer aided design (CAD), for an individual patient, but is not a shoe or shoe insert, will be covered by the statute.